

**From:** [Devlin, Robert](#)  
**To:** [Maryann Bassett](#); [Montilla, Tracey](#); [CN=Heidi Hiers/OU=RTP/O=USEPA/C=US@EPA](#); [Ghio, Andrew](#); [Martha Carraway](#); [Diaz-Sanchez, David](#)  
**Subject:** Warren Lux response to adverse event report  
**Date:** Monday, October 25, 2010 10:30:00 AM

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----- Forwarded by Robert Devlin/RTP/USEPA/US on 10/25/2010 10:28 AM -----

From: Warren Lux/DC/USEPA/US  
To: Robert Devlin/RTP/USEPA/US@EPA  
Cc: Howard Kehrl/RTP/USEPA/US@EPA  
Date: 10/21/2010 12:51 PM  
Subject: Re: IRB response to adverse event report

Bob,

PS: With regard to resuming exposures in this study, you have IRB clearance to proceed, and I concur with the IRB's determination.

Warren

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Warren Lux, M.D.  
Human Subjects Research Review Official and  
Director, Program in Human Research Ethics  
U.S. Environmental Protection Agency  
Ronald Reagan Building - Room 41248  
202-564-2677 or 202-564-3746 (direct)

From:  
Warren Lux/DC/USEPA/US

To:  
Robert Devlin/RTP/USEPA/US@EPA

Cc:  
Howard Kehrl/RTP/USEPA/US@EPA  
Date: 10/21/2010 12:47 PM

Subject: Re: IRB response to adverse event report

Bob,

[REDACTED]

Warren

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Warren Lux, M.D.  
Human Subjects Research Review Official and  
Director, Program in Human Research Ethics  
U.S. Environmental Protection Agency  
Ronald Reagan Building - Room 41248  
202-564-2677 or 202-564-3746 (direct)

From: Robert Devlin/RTP/USEPA/US  
To: Warren Lux/DC/USEPA/US@EPA  
Cc: Howard Kehrl/RTP/USEPA/US@EPA  
Date: 10/20/2010 03:27 PM  
Subject: IRB response to adverse event report

Warren:

[REDACTED]

[REDACTED]

----- Forwarded by Robert Devlin/RTP/USEPA/US on 10/20/2010 03:24 PM -----

From: IRB <irb\_no\_reply@mailserv.grad.unc.edu>

To: Robert Devlin/RTP/USEPA/US@EPA

Cc: Mike Schmitt/RTP/USEPA/US@EPA, Candice Bailey/RTP/USEPA/US@EPA, Robert Truckner/RTP/USEPA/US@EPA, wsimmons+IRB@med.unc.edu

Date: 10/20/2010 02:44 PM

Subject: IRB Notice

**To:** Robert Devlin  
Pediatrics  
CB: 7315

**From:** Biomedical IRB

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Authorized signature on behalf of IRB

**Date:** 10/20/2010

**RE:** IRB review of Unanticipated Problem report

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

CC:  
Mike Schmitt, Environmentally Protection Agency  
Candice Bailey, Epa  
Robert Truckner, (EPA), Non-IRB Review Contact  
Wanda Simmons, (CTRC), Non-IRB Review Contact

[REDACTED]

